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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,279	11/24/2003	Richard A. Hopkins	21486-027DIV	6395

7590 10/28/2005

MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.  
One Financial Center  
Boston, MA 02111

EXAMINER
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BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/722,279

Applicant(s)

HOPKINS ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-24 and 26-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-24 and 26-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Allowable Subject Matter***

1. Prosecution on the merits of this application is reopened on claims 21, 22, 26, 28-36, 39, and 41-44 are considered unpatentable for the reasons indicated below.

### ***Response to Amendment***

2. The declaration filed on April 16, 2005 under 37 CFR 1.131 is sufficient to overcome the Wolfinbarger, Jr. (US 6,432,712 B1) reference.
3. Applicants' amendment of claims 21-24, 28, 39, 40, 46, and 47 in the reply filed on April 16, 2005 is acknowledged.
4. Applicants' cancellation of claim 25 in the reply filed on April 16, 2005 is acknowledged.
5. Applicants' addition of claims 48-51 in the reply filed on April 16, 2005 is acknowledged.

### ***Drawings***

6. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 21-24 and 26-51 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Goldstein et al. (US 5,899,937 A) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goldstein et al. (US 5,899,937 A) in view of Bishopric et al. (US 5,855,620 A) and Vacanti et al. (US 6,348,069 B1).

Goldstein et al. disclose a method of manufacturing a bioprosthetic heart valve comprising:

(i) Providing an acellular or decellularized porcine valve (see column 1, lines 58-62; column 5, lines 24-26);

(ii) Seeding said acellular or decellularized porcine valve with isolated fibroblasts (i.e., dermal myofibroblasts; see column 1, line 61 to column 2, line 4; column 3, lines 11-13; column 6, lines 44-63; column 13, lines 7-11 and lines 15-24) wherein the myofibroblasts produce at least two-fold more type I collagen compared to type III collagen (see Abstract; column 1, lines 58-67; column 2, lines 1-67; column 6, lines 44-62; column 13, lines 7-11 and lines 20-24; column 14, line 65; see entire document); and,

(iii) Culturing said myofibroblasts under pulsatile flow conditions (see Abstract; see column 2, lines 50-53; column 3, lines 10-13; column 7, lines 53-67; column 9, lines 21-25; column 14, lines 27-37).

a. Goldstein et al. teach: "endothelial cells do not seem to be necessarily to prevent thrombus formation" (see column 6, lines 45-57). This is not an exclusive negative teaching. Further in Goldstein et al. specification, Goldstein et al. disclose known background directed to benefits using endothelial cells (see column 14, lines 43-56). While Goldstein does not deem it necessary

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(with respect to prevention of thrombosis) to use endothelial cells, this is not an inclusive bar against using endothelial cells in forming heart valves.

b. Bishopric et al. '620 teach that endothelial cells along with myofibroblasts (as well as other cell types) may be seeded on an acellularized matrix in vitro in order to form heart valves (see column 5, lines 33-36; column 6, lines 5-7; column 7, lines 50-67). Vacanti et al. '069 likewise teach that endothelial cells along with myofibroblasts (as well as other cell types) may be seeded on an acellularized matrix in vitro in order to form heart valves (see column 6, lines 25-35 and lines 40-43; column 7, line 60 to column 8, line 13). Vacanti et al. further teach that those cells can be "normal or genetically engineered to provide additional or normal function" (see column 6, lines 35-39). Looking to Applicant's specification, the endothelial cells and/or secretory cell are referred to as an option (i.e., no criticality), as disclosed at page 4, lines 14-16, and page 8, lines 5-6. Absence any showing of criticality, it was well known in the art (Bishopric et al. '620, and Vacanti et al. '069) to use more than one type of cell population in order to form heart valves.

### ***Response to Arguments***

9. Applicants' arguments filed April 16, 2005 have been fully considered but they are not persuasive. It is believed that Applicants' arguments have been adequately addressed in the 102(e) rejection above.

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*Conclusion*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Bader et al. (DE 198 28 726 A1), Hoerstrup et al. (DE 199 19 625 A1), Hoerstrup et al. (DE 102 35 237 A1), and Steinhoff, Gustav et al. "Tissue Engineering of Pulmonary Heart Valves on Allogenic Acellular Matrix Conduits" (Circulation: 2000; 102: III-50).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

October 25, 2005



David H. Willse  
Primary Examiner